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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,463	10/20/2003	Hans Michael Ockenfels	01840.0001-US-01	4148

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EXAMINER	
SHAY, DAVID M	

ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
12/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/689,463	OCKENFELS, HANS MICHAEL	
	Examiner	Art Unit	
	david shay	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *October 9, 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10,11 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10,11 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 9, 2007 has been entered.

Applicant argues that Anderson et al does not vary the UV radiation dose in dependence of the epidermal thickness of the skin areas affected by the disease." The examiner must respectfully disagree. The determination of the thickness of the epidermis is expressly taught by Anderson et al: "optical profilometry can measure skin thickness" (see column 8, lines 51-52). With regard to the varying of the dose, applicant asserts that Anderson et al demonstrates no such variation. The examiner first points out that according to the originally filed disclosure, the term "dose" is discussed as "The energy per pulse amounts to 4 mJ with the energy capable of being concentrated on a certain treatment area. Given a treatment area of 2 cm^2 this results in an energy density of 2 mJ/cm^2. The radiation **dose** can be varied between 100 and 6000 mJ/cm^2 in increments of 50 mJ/cm^2" (originally filed disclosure, page 5, lines 12-16, emphasis added), thus clearly the dose delivered to the plaque is described by an energy density, which is controlled by the number of pulses applied to the particular area. As detailed in the passage at column 15, lines 37-48 of Anderson et al, discussed in the previous office action, multiple pulses are applied to the plaque until the fluorescence is not detected, thus a variable dosage is applied, according to the thickness of the plaque at any particular point. As for the limitation of gradually varying the dose of radiation, the examiner notes, that while this phrase lacks antecedent basis in the originally filed disclosure, to the extent that it can be inferred in the instant application, this must

be due to and thus directly proportional to the variation in epidermal thickness of the skin, and since the method of Anderson et al also varies the dosage with the thickness of the skin, as discussed above with respect to the passage at column 15 thereof, this method must also vary the dosage gradually.

Applicant asserts that the passage at column 15 of Anderson et al teaches that Anderson et al apply doses "to subsequent areas until the diagnostic ratios indicate that the scanned area is not an affected area" (emphasis in original), and apparently concludes that this passage teaches that after treating the patient, an area should be diagnosed; and if psioratic, treated; and thereafter ignored, without further diagnosis to determine if futher treatment is merited. It is unclear why applicant feels that one of ordinary skill in the art would prefer to leave an area not fully treated, especially after going back and performing a subsequent diagnosis and treatment, however it is the examiner's view that, one of ordinary skill in the art would never follow this course of action, simply for malpractice reasons, and applicant has demonstrated no reason why one of ordinary skill in the art would do so. Further, in lines 49-52 of column 15 Anderson et al teach "the computer can vary the fluence of the therapeutic dose for each treatment area…according to the differences of the diagnostic ratios". Thus applicant's arguments are not convincing.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment filed October 10, 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not

supported by the original disclosure is as follows: "gradually varying a UV radiation dose per treatment generated by a laser from the first skin area to the second skin area".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 68-94 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure is silent on "gradually varying a UV radiation dose per treatment generated by a laser from the first skin area to the second skin area".

Claims 1, 2, 3-8, 10, 11, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the claims, the term "gradually varying a UV radiation dose per treatment generated by a laser from the first skin area to the second skin area" lacks positive antecedent basis in the originally filed disclosure, as such the exact meaning of this term is unclear.

Claims 1, 2, 4-7, 11, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al in combination with Chernoff, Sator et al and Neigut. Anderson et al teaches treatment of psoriasis wherein the skin is tested, e.g. by determining skin thickness to determine psoriatic areas and the areas are exposed to treatment radiation, preferably so as not to cause blister formation, wherein the fluorescence generated by the treatment pulse is used to

determine whether or not an additional treatment pulse should be directed to the plaque (see column 15, lines 37-48). Chernoff teaches a device and method for treating the skin wherein the skin depth is determined at each point of treatment and the treatment laser power is adjusted for the depth at each point. Sator et al teach that PUVA treated skin experiences accelerated thinning, which is correlated with the PUVA compared to the skin of people who have not undergone PUVA and that ultrasound is a sensitive and non-invasive method for determining skin thickness. Neigut teaches that psoriatic plaques reduce with treatment (see column 13, lines 14-34). It would have been obvious to the artisan or ordinary skill to use ultrasound to measure the skin thickness of patients in the method of Anderson et al, since this is a sensitive and non-invasive measure, as taught by Sato et al, and to employ the laser-ultrasound cooperation steps of Chernoff in the method, since this would enable the dosages to be minimized for each patient by preventing the dosing of unaffected skin, and to vary the dosage with each treatment, since treatments reduce the plaques, thus reducing the required dosage to treat them under the regimen of Anderson et al, thus producing a device and method such as claimed.

Claims 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al in combination with Chernoff, Sator et al, and Neigut as applied to claims 1, 2, 4-7, 11, and 14 above, and further in combination with Mueller et al. Mueller et al teach the incorporation of a laser and ultrasound applicator in a single instrument. It would have been obvious to the artisan of ordinary skill to provide the laser and ultrasound applicator in the combined method of Anderson et al in combination with Chernoff and Sator et al, since the separated ultrasound and laser applicators and combined applicators are equivalents, as shown by Mueller et al, or, alternatively, to employ the combined method of Anderson et al in combination

with Chernoff and Sator et al in the method of Mueller et al, since Mueller et al discuss no therapy for any particular condition and in either case, to employ a mirror arm to conduct the radiation, since this is equivalent to the use of fiber optics and can more efficiently transmit ultraviolet light, official notice of which is hereby taken, thus producing a device such as claimed.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al in combination with Chernoff, Sator et al, and Neigut as applied to claims 1, 2, 4-7, 11, and 14 above, and further in combination with Bonis et al. Bonis et al teach increasing the dosage of UV light in psoriasis plaques that do not respond to a base level of therapy, and continuing the increase until a response is seen. It would have been obvious to the artisan of ordinary skill to employ the dosage increase technique of Bonis et al in the combined method of Anderson et al in combination with Chernoff and Sator et al, since this yields better results, as taught by Bonis et al, thus producing a method and device such as claimed.

Applicant's arguments filed October 9, 2007 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/

Primary Examiner, Art Unit 3735